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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,290	04/12/2000	Tatsuya Sasakawa	0018-1098-0	6669

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EXAMINER	
BECKERLEG, ANNE M	
ART UNIT	**PAPER NUMBER**
1632	9

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,290	SASAKAWA ET AL.	
	Examiner	Art Unit	
	Anne Marie Becherleg	1632	

-- The MAILING DATE of this communication app ars on the cov r she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Applicant's amendment received on 4/1/02 has been entered. Claims 1-20 have been canceled. New claims 21-28 have been added. Claims 21-28 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Claim Rejections - 35 USC § 112

The rejection of canceled claims 1-20 under 35 U.S.C. 112, first paragraph, is maintained over newly added claims 21-28 for reasons of record. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The previous office action stated that the specification, while being enabling for a mouse model of atopic dermatitis comprising an NC/nga mouse raised under specific pathogen free conditions which has been exposed to a mite or mite extract, and methods of using said mouse model to screen for therapeutic agents effective against atopic dermatitis, does not reasonably provide enablement for the generation of any type of animal model for atopic dermatitis which

comprises the exposure of any type of animal under specific pathogen free conditions to any allergen.

The applicant argues that the new claims obviate the rejection of record as the specification provides a detail description of an NC/Nga mouse impregnated with an extract of an antigen. Please note that applicant's have previously elected with traverse the species of atopic dermatitis for examination in the instant application. The applicant's newly added claims are still broad and continue to read on an NC/Nga mouse model for any allergic disorder. Further, the previous office action stated that the specification does not provide an enabling disclosure for producing symptoms of atopic dermatitis in specific pathogen free NC/nga mice using any allergen other than a mite or mite extract. The art at the time of filing teaches that NC/nga mice when raised under conventional conditions spontaneously develop skin lesions. The art speculates that this reaction in the NC/nga mice is caused by environmental antigens. The art further teaches that humans with atopic dermatitis exhibit extreme hypersensitivity to mite antigens, and that the exposure of specific pathogen free NC/nga mice to mites results in skin lesions. At the time of filing, the art had not identified any other environmental antigen associated with the development of atopic dermatitis. The specification fails to provide any additional information as to the identity or characteristics of any other allergen other than a mite which is implicated or been demonstrated to be associated with the development of atopic dermatitis. In the absence of any disclosure by the specification or the prior art, the skilled artisan would not have any idea which of the innumerable potential environmental antigens might be responsible for generating atopic

dermatitis like symptoms in NC/nga mice. Further, the applicant is reminded that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. *In re Goodman*, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing *In re Vaeck*, 20 USPQ2d at 1445 (Fed. Cir. 1991). Ultimately, case law states that ".. the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves." *In re Gardner 166* USPQ 138 (CCPA) 1970. Thus, based on the unknown nature of the allergens responsible for the development of spontaneous atopic dermatitis like symptoms in NC/nga mice, the limitation of the specification's disclosure and working examples to mite allergens, and the breadth of the claims, it would have required undue experimentation to practice the scope of the invention as claimed.

Applicant's cancellation of claims 1-16 and 18-19 has rendered moot the rejection of these claims under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

Applicant's cancellation of claims 1-11 and 13-14 has rendered moot the rejection of these claims under 35 U.S.C. 102(b) as being anticipated by Morita et al.

Claim Rejections - 35 USC § 103

The rejection of canceled claims 1 and 12 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. in view of Yasue et al. is maintained over new claims 21-26. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that Morita et al. does not teach the specific pathogen free (SPF) condition recited in the claims because Morita administered live mites to the model mice. However, Morita et al. clearly teaches NC mice, an inbred strain of fancy mice established in 1955, which have been bred under specific pathogen free conditions and renamed NC/kuj. The fact that these mice bred under SPF conditions are then administered a live mite does not detract from the teachings of breeding and maintaining these NC/kuj mice under SPF conditions. Further, in regards to the argument that the claimed mouse has several advantages as compared to the mouse described by Morita et al., the rejection of record is not based solely on the teachings of Morita et al., but on the combination of Morita et al. and Yasue et al.

In regards to the teachings of Yasue et al., the applicant does not contest that Yasue et al. teaches administration of crude mite extract to mice. However, the applicant does argue that neither Morita or Yasue provide motivation for combining the teachings of the two references to suggest the instant invention. The applicant states that the office has not provided any evidence of motivation for combining the administration of mite extract with the method of making a mouse

model for atopic dermatitis taught by Morita et al. which uses live mites. The previous office action, however, clearly stated that the skilled artisan would be motivated to use a mite extract over live mites in order to standardize the amount of antigen to which each mouse is exposed, thereby ensuring a homogenous population of exposed mice. Thus, in order to produce a more homogeneous population of mite sensitized mice for use as an animal model of human allergic disease, it would have been prima facie obvious to the skilled artisan to substitute mite extract injection as taught by Yasue et al. for the live mite exposure taught by Morita et al. in the method of producing a murine model of atopic dermatitis taught by Morita et al. Further, based on the successful use of mite extracts to generate allergic responses in mice as taught by Yasue et al., the skilled artisan would have had a reasonable expectation of success in generating a mouse model of atopic dermatitis by exposing specific pathogen free NC mice to a mite extract. It is noted, that the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). For the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988). Also, "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include

knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin*, 443 F2d. 1392, 170 USPQ 209, 212 (CCPA 1971).

The rejection of canceled claims 15-16 and 18-19 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. in view of Yasue et al. and Hiroi et al. is maintained over new claims 27 and 28. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that Hiroi et al. does not remedy the deficiencies of the combination of Morita et al. and Yasue et al. as discussed by the applicants in the rejection of the canceled claims 1 and 12 over the combination of Morita and Yasue. Applicant's arguments concerning the teachings of Morita et al. and Yasue et al. have been addressed in detail above. In regards to the combination of Morita et al. and Hiroi et al., the previous office action stated that Morita et al. teaches that the administration of ivermectin to the mice reduces anti-mite IgE levels and skin lesions (Morita et al., pages 41-42). This demonstrates that the mice are suitable for testing potential therapeutic agents. Hiroi et al. further supplements Morita et al. by providing motivation for testing potential therapeutic agents in mouse models of atopic dermatitis. Hiroi teaches that the standard model for spontaneous atopic dermatitis, NC mice raised under conventional and not specific pathogen free conditions, can be used to screen for therapeutic agents. Specifically, Hiroi teaches that FK506 ointment, not betamethasone valerate ointment, was determined to be

effective in suppressing and inhibiting symptoms of atopic dermatitis when applied to NC mice both before and after the development of dermatological symptoms (Hiroi et al., page 176 and Figure 1, 2, and 3). Thus, in view of the motivation provided by Hiroi et al. for using murine models of atopic dermatitis to determine the effectiveness of agents in preventing or inhibiting atopic dermatitis, it would have been prima facie obvious to use the screen agents for effectiveness against atopic dermatitis using the mouse model taught by Morita et al. Further, based on the demonstration by Morita et al. that ivermectin is useful for treating atopic dermatitis like symptoms in the mouse model of atopic dermatitis developed by Morita et al., the skilled artisan would have had a reasonable expectation of success in testing agents for effectiveness against atopic dermatitis using the mouse model taught by Morita et al. The applicant has not provided any specific arguments which address the teachings of Hiroi et al.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbe, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbe